## REMARKS

Claims 1-42 are now pending in the application. Claims 1, 20, 21 and 38-40 are currently amended; claims 2-19, 22-37 and 41-42 are original. A copy of the claims now pending in the application showing changes made to currently amended claims in accord with 37 CFR §1.121, as revised, has been provided. No new matter has been introduced by virtue of the amendments made herein. Accordingly, applicants respectfully request their entry. In view of the amendments made herein and the remarks below, applicants respectfully request reconsideration and withdrawal of the rejection set forth in the June 18, 2003 office action.

**Rejection under 35 USC § 103(a)**

The Examiner rejected claims 1-12 and 15-42 under 35 USC § 103(a) as being unpatentable over EP 436 370 (Noda et al.) in view of WO 00/32589 (Dallman et al.).

The applicants' previous argument that Noda et al. teach "a controlled release pharmaceutical preparation which comprises (a) a core containing a pharmaceutically active substance *and an organic acid*" (see col. 2, l. 29 - 31 and the Examples) and that therefore Noda et al. teach away from the instant claims which do not recite an organic acid in the core was rejected by the Examiner. The Examiner stated that "the instant claims are written with open language, thereby not excluding the presence of an organic acid."

Without prejudice and in the interests of facilitating prosecution, and for the sake of clarity, the applicants have herein amended claim 1 to recite "and with the core not containing an organic acid." Support for this amendment can be found at page 4, lines 31-32. In addition, without prejudice and in the interests of facilitating prosecution, and for the sake of clarity, applicants have amended claims 20 and 21 by deletion of the phrase "eletriptan or a pharmaceutically acceptable salt thereof" and insertion in its place of the phrase "the pharmaceutical composition of claim 1."

Without prejudice, and in the interests of facilitating prosecution, and for the sake of clarity, applicants have also amended claims 38-40. Amended claim 38 recites: "A method of administering eletriptan or a pharmaceutically acceptable salt thereof, ... which comprises delivering eletriptan or a pharmaceutically acceptable salt thereof, in the absence of an organic acid." Amended claim 39 recites: "A method of administering eletriptan or a pharmaceutically

acceptable salt thereof, ... which comprises delivering, in the absence of an organic acid." Amended claim 40 recites: "A sigmoidal controlled release pharmaceutical composition containing eletriptan or a pharmaceutically acceptable salt thereof that does not contain an organic acid."

Applicants submit that Noda et al. who require an organic acid in the core teach away from the instant claims, as amended, which exclude an organic acid in the core. As stated by the Examiner, Noda et al. do not specifically teach eletriptan as the active agent in the formulation. Applicants submit that combining Noda et al. and Dallman et al. in the manner suggested by the Examiner cannot produce the composition recited by amended claim 1, the formulations of amended claims 20-23, which now incorporate the features of the composition of amended claim 1, the methods of amended claims 38 and 39 or the composition of amended claim 40.

Applicants submit that amended claims 1, 20, 21 and 38-40 are patentable under 35 USC § 103(a) over the cited references, either separately or in the combination cited by the Examiner, and respectfully request withdrawal of the rejection. Applicants further submit that claims 2-12, 15-19, 22-37 and 41-42, all of which directly or indirectly incorporate the novel and unobvious features of amended claims 1, 20, 21 and 38-40, are all patentable under 35 USC § 103(a) over the cited references, either separately or in the combination cited by the Examiner, and respectfully request withdrawal of the rejection.

The Examiner also rejected claims 1, 2, 4-9, 15, 17, 18, 20-42 under 35 USC § 103(a) as being unpatentable over "An Organic Acid Induced Sigmoidal Release System for Oral Controlled Release Preparations" by Narisawa et al. in view of WO 00/32589 (Dallman et al.). Applicants submit that the controlled release system studied by Narisawa et al. contains an organic acid in the drug-containing core which is termed the "bead" in Narisawa et al. (see page 86, 1st col., lines 8 and 9, section 2.2 ("Preparation of SRS") and page 91, Fig. 6).

Applicants submit that Narisawa et al. teach away from the instant claims, as amended, which exclude an organic acid in the core, compositions, formulations and methods as discussed above. As stated by the Examiner, Narisawa et al. do not specifically teach eletriptan as the active agent in the formulation. Applicants submit that combining Narisawa et al. and Dallman et al. in the manner suggested by the Examiner cannot produce the composition recited by amended claim 1, the formulations of amended claims 20-23, which now incorporate the features

of the composition of amended claim 1, the methods of amended claims 38 and 39 or the composition of amended claim 40.

Applicants submit amended claims 1, 20, 21 and 38-40 are patentable under 35 USC § 103(a) over the cited references, either separately or in the combination cited by the Examiner, and respectfully request withdrawal of the rejection. Applicants further submit that claims 2, 4-9, 15, 17, 18, 22-37 and 41-42, all of which directly or indirectly incorporate the novel and unobvious features of amended claims 1, 20, 21 and 38-40, are all patentable under 35 USC § 103(a) over the cited references, either separately or in the combination cited by the Examiner, and respectfully request withdrawal of the rejection.

In view of the remarks above, applicants respectfully submit that the pending claims are fully allowable, and therefore solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicants' undersigned attorney at the telephone number provided.

The Commissioner is hereby authorized to charge any fee required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445.

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A. David Joran
Attorney for Applicant(s)
Reg. No. 37,858

Pfizer Inc
Patent Department
150 East 42nd Street – 5th Floor
New York, NY 10017-5755
(212) 733-3381